



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/564,712                           | 01/12/2006  | Werner Baschong      | HU/15-22918/A/PCT   | 9870             |
| 324                                  | 7590        | 11/08/2007           | EXAMINER            |                  |
| CIBA SPECIALTY CHEMICALS CORPORATION |             |                      | WESTERBERG, NISSA M |                  |
| PATENT DEPARTMENT                    |             |                      |                     |                  |
| 540 WHITE PLAINS RD                  |             |                      | ART UNIT            | PAPER NUMBER     |
| P O BOX 2005                         |             |                      | 4173                |                  |
| TARRYTOWN, NY 10591-9005             |             |                      |                     |                  |
|                                      |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                      |             |                      | 11/08/2007          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/564,712             | BASCHONG ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Nissa M. Westerberg    | 4173                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 - 19, 21 - 29 is/are pending in the application.
- 4a) Of the above claim(s) 7, 13, 15 - 19, 21 - 29 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 - 6, 8 - 12, 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1 sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election of a halogenated hydroxydiphenyl ether compound of component (a) as the compound of formula 3; the presence of a second skin lightening substant of component (b) as kojic acid and the presence of a UV-A or UV-B absorber of component (c) as the compound of formula (5e) in the reply filed on October 22, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

***Status of Claims***

Claims 1 – 19 and 21 – 29 are pending. Claim 20 has been cancelled. Claims 7, 13, 15 – 19 and 21 – 29 are withdrawn as being drawn to the non-elected invention. Claims 1 – 6, 8 – 12 and 14 are currently under examination.

***Comments and Notes***

In the currently amended claim 11, it appears that "%" should have been deleted. As currently amended, the claim recites "the ratio of components (a):(b) is from 1 : 99 to

99 : 1% by weight." It has been assumed that the claim should recite a ratio of the components (a):(b) by weight should be 1:99 to 99:1.

The elected species compound of formula (3) is the compound that is commonly known as triclosan or 2,4,4'-trichloro-2'-hydroxydiphenyl ether. The elected species compound of formula (5e) is 2-4-bis{[4-(2-ethyl-hexyloxy)-2-hydroxy]-phenyl}-6-[4-(2-methoxyethyl-carboxyl)-phenyl- amino]-1,3,5-triazine or TINASORB S®.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the term "L\*" is used on p 34 but no explanation of this term is provided.

Appropriate correction is required.

3. The use of the trademarks such as "Jaguar" and "Mirasol" have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible trademarks and abbreviations that are present without the full name being spelled out. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 4173

7. Claims 1 – 6, 8 – 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hague (WO 01/70189) in view of Sakoda et al. (WO 98/17247) and Ashby et al. (Regul Toxicol Pharmacol 34(3), p 287 - 291, 2001).

Hague discloses methods and compositions for lightening the color of skin (p 1, In 4 – 5). A composition comprising about 0.1 to about 15% by weight of an alpha- or beta-hydroxy carboxylic acid, from about 0.01 to about 5% by weight of an anti-microbial agent, about 0.1 to about 30% by weight of a sunscreen agent and a pharmaceutically acceptable carrier (p 3, In 1 – 9). Triclosan is exemplified as a preferred antibacterial agent on p 8, In 27. The ratio of triclosan (component (a) of the instant application) to the skin lightening component (component (b) of the instant application) can range from 1:1500 to 50:1. Alpha-hydroxy carboxylic acid salts such as lactic acid can cause irritation of the skin, particularly at higher levels of use (p 2, In 4 – 9).

Example compositions 1, 2, 6 and 8 (p 20) comprise triclosan and lactic acid (an alpha-hydroxy carboxylic acid) and/or salicyclic acid (a beta-hydroxy carboxylic acid). In a clinical trial, compositions further comprising triclosan were found to be more effective in reducing hyperpigmentation or lightening the skin than compositions without triclosan with the same amounts of lactic acid and salicyclic acid (p 21, Table I, In 25 – 28).

Example 11 (p 23) discloses a skin lotion comprising PARSOL MCX® (an organic sunscreen, Table I, p 12), salicylic acid, lactic acid and triclosan. In this composition, the ratio of triclosan:skin lightening ingredients (salicylic acid and lactic acid) is 1:7.5 based on the weight % of the individual components.

Hague does not teach kojic acid or TINOSORB S® as possible components for a composition or for use in skin lightening methods. It also does not teach a method of using a composition for the skin lightening and the simultaneous antimicrobial treatment of the skin, mucosa and/or integumentary appendages (hair).

Sakoda et al. discloses compositions comprising kojic acid and salicyclic acid. The composition is useful for lightening mammalian skin (p 2, In 4 – 19). Kojic acid inhibits the formation of melanin (melanogenesis) and is used as a skin lightening ingredient (p 2, In 22 – 28). Optional ingredients include sunscreens such as water-soluble ultraviolet and infrared screening and absorbing agents to screen and absorb ultraviolet and infrared light (p 6, In 17 – 22). The compositions comprising kojic acid and salicyclic acid are applied to skin for the purposes of lightening mammalian skin (p 9, In 23 – 28).

Ashby et al. discloses that the sunscreens TINOSORB® M-active and TINOSORB S® do not appear to have estrogenic or androgenic activity and are unlikely to act as hormonal mimics in mammals (p 290, col 1 second paragraph – col 2). Concerns have been raised about the possibility of environmental chemicals such as sunscreens to disrupt the function of sex hormones and the endocrine system (p 287, col 1, first paragraph).

Both Hague and Sakoda et al. teaches compositions comprising salicyclic acid that can be used in methods for lightening the skin. Hague teaches that the addition of triclosan to the composition results in a composition with greater efficacy in reducing in hyperpigmentation and lightening the skin. Also, given the teachings of possible skin

irritation by alpha-hydroxy carboxylic acids, one of ordinary skill would have been motivated to replace these ingredients with other ingredients such as kojic acid. One of ordinary skill in the art at the time of the instant invention would have been motivated to add triclosan to other compositions designed for lightening the skin to see if similar effects are seen with other combinations of skin lightening ingredients. For example, adding triclosan to the combination of salicyclic acid and kojic acid taught by Sakoda et al. Triclosan is known as an anti-microbial agent so the use of a composition containing an anti-microbial agent for the antimicrobial treatment of the skin, mucosa and/or hair would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Given the concerns about endocrine disruption in mammals by organic sunscreen agents as disclosed by Ashby et al., one of ordinary skill in the art at the time of the instant invention would be motivated to replace sunscreen agents with endocrine disruption activity with a sunscreen agent such as TINOSORB S® that has been shown not to have these effects.

Therefore, the combined teachings of Hague, Sakoda et al. and Ashby et al. render obvious the use of a skin lightening composition with triclosan, kojic acid and the non-endocrine disruptive sunscreen TINOSORB S® in a method to lighten the skin and inhibit the melanogenesis as well as for the anti-microbial treatment of the skin, mucosa and/or hair.

***Conclusion***

Claims 1 – 6, 8 – 12 and 14 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571) 270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

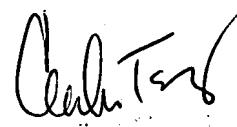
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/564,712

Page 9

Art Unit: 4173

NMW

A handwritten signature in black ink, appearing to read "Charles Teng". The signature is fluid and cursive, with a prominent "C" at the beginning.